TIME SENSITIVE PATENT INFORMATION PURSUANT TO 21 C.F.R. 314.53 (c) FOR NDA # 20-553

The following is provided in accordance with the Drug Price Competition and Patent Term Restoration Act of 1984:

Trade Name:

OxyContin®

Active Ingredient(s):

Oxycodone Hydrochloride 10, 20, 40, 80 and 160 mg

Strength(s):
Dosage Form:

Extended-Release Tablets

Approval Date:

10 mg. - December 12, 1995 20 mg. - December 12, 1995 40 mg. - December 12, 1995

80 mg. – January 6, 1997 160 mg. – March 15, 2000

Applicant:

Purdue Pharma L.P.

One Stamford Forum Stamford, CT 06901-3431

Listed Drug:

OxyContin® (Oxycodone Hydrocloride) Controlled-Release Tablets

Indication(s):

OxyContin® (Oxycodone Hydrocloride) Controlled-Release Tablets are indicated for the management of moderate to severe pain when a continuous,

around-the-clock analgesic is needed for an extended period of time.

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Trial Exhibit

Purdue et al. v. Endo et al.

Nos. 00 Civ. 8029 (SHS);

01 Civ. 2109 (SHS); 01 Civ. 8177 (SHS)

DX 4110

1.

United	States Patent No. 4,861	,598	
A	This information should be provided for each individual patent submitted:		
	U.S. Patent Number:	<u>4,861,598</u>	
	Expiration Date:	August 29, 2006	
	Type of Patent (indicate all that apply):		
	Drug Substance (Active Ingredient) Drug Product (Composition/Formulation) Method of Use Y X N Y N Y X N		
	a. If patent claim method(s) of u N/A	s method(s) of use, please specify approved method(s) of use or e for which approval is being sought that are covered by patent:	
Name of Patent Owner: Euro-Celtique S.A.			
U.S. A	gent (if patent owner or C. Strassburger, Purdue)	applicant does not reside or have place of business in the U.S.): Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431	
В.	The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.		
	The undersigned declares that the above stated United States Number 4,861,598 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:		
	x currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.		
	OR		
	the subject of this application for which approval is being sought.		

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Purdue v. Endo

2.

United	States Patent No. 4,970,075		
A.	This information should be provided for each individual patent submitted:		
	U.S. Patent Number:	4,970,075	
	Expiration Date:	August 29, 2006	
Type of Patent (indicate all that apply): Drug Substance (Active Ingredient) Y X N Drug Product (Composition/Formulation) X Y N Method of Use Y X N		t apply):	
		rmulation) Y X N X Y N Y X N	
	a. If patent claims method method(s) of use for wind.	d(s) of use, please specify approved method(s) of use or hich approval is being sought that are covered by patent:	
Name	of Patent Owner:	Euro-Celtique S.A.	
U.S. A	gent (if patent owner or applicate C. Strassburger, Purdue Pharma	nt does not reside or have place of business in the U.S.): L.P., 1 Stamford Forum, Stamford, CT 06901-3431	
В.	The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims		
The undersigned declares that the above stated United States Number 4,970,075 the composition, formulation and/or method of use of all strengths of OxyC Controlled-Release Tablets. This product is:		and/or method of use of all strengths of OxyContine	
		section 505 of the Federal Food, Drug and Cosmetic Act.	
	OR		
	the subject of this application for which approval is being sought.		

Confidential Information <u>Purdue v. Endo</u> 3.

United States Patent No. 5,266,331			
A.	This information should be provided for each individual patent submitted:		
	U.S. P	atent Number:	<u>5,266,331</u>
	Ехріга	ation Date:	October 26, 2007
	Type of Patent (indicate all that		hat apply):
	Drug Substance (Active Ingredient) Drug Product (Composition/Formulation) Method of Use Y X N X Y N Y X N		
	a. If patent claims method(s) of use, please specify approved method(s) of use method(s) of use for which approval is being sought that are covered by pater N/A		nod(s) of use, please specify approved method(s) of use or which approval is being sought that are covered by patent:
Name of Patent Owner: Purdue Pharma L.P. The Purdue Frederick Company The P.F. Laboratories, Inc. The Purdue Pharma Company			The Purdue Frederick Company
U.S. Agent (if patent owner or applicant does not reside or have place of business in the U.S.): Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431			
В	The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.		
	The undersigned declares that the above stated United States Number 5,266,331 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:		
	x currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.		
	OR		
the subject of this application for which approval is being sought.			

Confidential Information
<u>Purdue v. Endo</u>

United	States	Patent No. 5,508,	042		
Α.	This in	This information should be provided for each individual patent submitted:			
	U.S. P	atent Number:	5,508.042		
	Expira	tion Date:	April 16, 201	13	
	Type	of Patent (indicate	all that apply):		
	Drug I	Substance (Active) Product (Composit d of Use	Ingredient) ion/Formulation)	Y X N Y X N	
	a .	method(s) of use Management of	for which approval	is being sought that are covered by patents: pain when a continuous, around-the-cluperiod of time.	<u> </u>
Name	of Paten	it Owner:	The P.F. Lat	rma L.P. Frederick Company boratories, Inc. Pharma Company	
U.S. A	gent (if C. Stras	patent owner or a sburger, Purdue Pl	pplicant does not res harma L.P., 1 Stamfo	side or have place of business in the U.S.) ord Forum. Stamford. CT 06901-3431	: ——
В.	The fo	ollowing declarati	on statement is req	quired by 21 C.F.R. 314.53. If any of lation or Method of Use claims, it should position/formulation or method of use claims.	u ve
	The undersigned declares that the above stated United States Number 5,508,042 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:				
	<u>x</u> c	urrently approved	under section 505 of	of the Federal Food, Drug and Cosmetic A	,ct.
	OR				
	th	c subject of this ap	pplication for which	approval is being sought.	

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Purdue v. Endo

5.	Unite	d States Patent No. 5,549,91	2
	A.	This information should be	provided for each individual patent submitted:
		U.S. Patent Number:	<u>5,549.912</u>
		Expiration Date:	October 26, 2007
		Type of Patent (indicate al	l that apply):
		Drug Substance (Active In Drug Product (Composition Method of Use	gredient) Y X N n/Formulation) X Y N Y X N
		a. If patent claims in method(s) of use f	nethod(s) of use, please specify approved method(s) of use or or which approval is being sought that are covered by patent:
	Name	e of Patent Owner:	Purdue Pharma L.P.
	149DIV		The Purdue Frederick Company
	•		The P.F. Laboratories, Inc.
			The Purdue Pharma Company
	U.S. Phili	Agent (if patent owner or app p.C. Strassburger, Purdue Pha	olicant does not reside or have place of husiness in the U.S.): 1777 TIME L.P., 1 Stamford Forum, Stamford, CT 06901-3431
	В.	The following declaration	n statement is required by 21 C.F.R. 314.53. If any of the emposition/Formulation or Method of Use claims, it should be that contains composition/formulation or method of use claims.
		The undersigned declares the composition, formula Controlled-Release Tablet	that the above stated United States Number 5,549,912 coveration and/or method of use of all strengths of OxyContinus. This product is:
		x currently approved u	nder section 505 of the Federal Food, Drug and Cosmetic Act.

the subject of this application for which approval is being sought.

OR

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6. United States Patent No. 5,65	6,295
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Drug Substance (Active Ingredient)

A.	This information should be provided for each individual patent submitted:		
	U.S. Patent Number:	<u>5,656,295</u>	
	Expiration Date:	October 26, 2007	
	Type of Patent (indicate all that apply):		

	Product (Composition/Formulation) od of Use	$\frac{\mathbf{x}}{\mathbf{x}}$
_	If natent claims method(s) of use. I	please specify approved me

a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent:

Management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

Name of Patent Owner:

Purduc Pharma L.P.

The Purdue Frederick Company The P.F. Laboratories, Inc. The Purdue Pharma Company

U.S. Agent (if patent owner or applicant does not reside or have place of business in the U.S.): Philip C. Strassburger. Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

B. The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 5,656,295 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

x currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

the subject of this application for which approval is being sought.

Signed:

Philip C. Strassburger

U.S. Patent and Trademark Office Registration No. 34,258

Date: March 28, 2002

Title: Vice President, Intellectual Property Counsel

Purdue Pharma L.P.

Telephone Number: (2

(203) 588-7639

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